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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,201	09/22/2003	Janos Kreidl	22631	7183

535 7590 10/05/2005

THE FIRM OF KARL F ROSS  
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EXAMINER

STOCKTON, LAURA

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/667,201	<b>Applicant(s)</b> KREIDL ET AL.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☒ Claim(s) 9 and 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/22/03</u> . | 6) <input type="checkbox"/> Other: ____.  |

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Art Unit: 1626

**DETAILED ACTION**

**Claims 1-10 are pending in the application.**

***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Hungary on March 23, 2001. It is noted, however, that applicant has not filed a certified copy of the Hungarian application as required by 35 U.S.C. 119(b).

***Information Disclosure Statement***

The Information Disclosure Statement filed on September 22, 2003 has been considered by the Examiner.

Art Unit: 1626

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al. {U.S. Pat. 5,371,101} in view of Gu et al. {Journal of Pharmaceutical Sciences, Vol. 84, No. 12, December 1995, pages 1438-1441}, Kreidl et al. {U.S. Pat. 5,707,976}, and Clive et al. {U.S. Pat 5,872,258}.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim a process of making a fluconazole of formula (I) by hydrolyzing a silyl ether compound of formula (II). Itoh et al. teach a process of hydrolyzing a silyl ether compound (VII) to produce the

Art Unit: 1626

hydroxy compound of formula (X) {see column 1, lines 25-49; column 6, lines 5-13, 25-39; column 7, lines 54-68; and column 8, lines 1-5}.

***Ascertainment of the difference between the prior art and the claims  
(MPEP §2141.02)***

The difference between the process of Itoh et al. and the process instantly claimed is the use of analogous reactants.

***Finding of prima facie obviousness--rational and motivation (MPEP  
§2142-2413)***

The use of analogous reactants in a known process is *prima facie* obvious. In re Durden, 226 USPQ 359 (1985). The instant starting material of formula (II) is known as seen in Kreidl et al. (column 1, lines 15-48; and especially Example 2 in column 7); and the product of formula (I) produced by the instant claimed process is known as seen in Kreidl et al. (column 2,

Art Unit: 1626

lines 1-11), Gu et al. (page 1438, top of second column) and Clive et al. (column 1, lines 13-27).

Once the general reaction has been shown to be old, the burden is on Applicants to present reasons or authority for believing that a group on the starting material would take part in or affect the basic reaction and thus alter the nature of the product or the operability of the process. In looking at the instant claimed process as a whole, as stated in In re Ochiai, 37 USPQ 2d 1127 (1995), the claimed process would have been suggested to one skilled in the art.

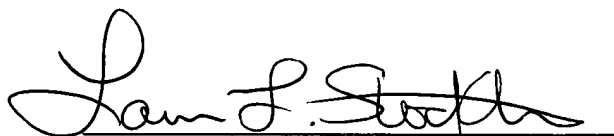
Claims 9 and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1626

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.  
Patent Examiner  
Art Unit 1626, Group 1620  
Technology Center 1600

October 3, 2005